AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for preparing a meningococcal conjugate vaccine in commercial volumes, the method comprising:

reacting a meningococcal polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained;

reacting a meningococcal protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained;

purifying said solution of hydrazine-activated protein under conditions standardized to process at least five liters of solution;

reacting the aldehyde-activated polysaccharide with the hydrazine-activated protein at a pH of from 5 to 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained;

neutralizing unreacted aldehyde groups with adipic acid dihydrazide; and

purifying the resulting solution under conditions standardized to process a volume of at least two liters,

whereby a meningococcal conjugate vaccine capable of stimulating an immune response is obtained in commercial volumes.

2. (Original) The method according to claim 1, wherein the oxidizing agent comprises $NaIO_4$.

3. (Original) The method according to claim 1, wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged with a HEPES buffer.

4. (Previously Presented) The method according to claim 1, wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged to a pH from 7 to 8.

5. (Original) The method according to claim 1, wherein the solution of the hydrazine-activated protein is buffer exchanged with a Na_2CO_3 buffer.

6. (Previously Presented) The method according to claim 1, wherein the solution of the hydrazine-activated protein is buffer exchanged to a pH from 10.0 to 11.0.

7. (Previously Presented) The method according to claim 6, wherein a pH of the solution of the hydrazine-activated protein is raised from 7.0 to 11 before the solution of the hydrazine-activated protein is buffer exchanged to a pH from 10.0 to 11.0.

8. (Previously Presented) The method according to claim 1, wherein the aldehyde-activated polysaccharide is reacted with the hydrazine-activated protein at a ratio from 1:1.6 to 1:5.

9. (Currently Amended) The method according to claim 1, wherein said purifying the resulting solution comprises the step of diafiltrating the meningococcal conjugate vaccine, whereby ~~substantially all~~ unreacted compounds and unconjugated polysaccharides are removed, yielding a purified conjugate vaccine.

10. (Original) The method according to claim 9, further comprising the step of concentrating the purified conjugate vaccine by tangential flow ultrafiltration, yielding a concentrated purified conjugate vaccine.

11. (Original) The method according to claim 10, further comprising the step of adding saccharose as a stabilizer to the concentrated purified conjugate vaccine, yielding a stabilized conjugate vaccine.

12. (Original) The method according to claim 10, further comprising the step of freeze drying the concentrated purified conjugate vaccine, yielding a dried conjugate vaccine.

Claims 13-14 (Cancelled).

15. (Currently Amended) A method for preparing a meningococcal conjugate vaccine in commercial volumes, the method comprising:

reacting a meningococcal polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained;

buffer exchanging the solution of the aldehyde-activated polysaccharide to a pH from about 7 to 8;

reacting a meningococcal protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained;

raising a pH of the solution of the hydrazine-activated protein from 7.0 to 11 and thereafter buffer exchanging the solution of the hydrazine-activated protein to a pH from 10.0 to 11.0;

purifying said solution of hydrazine-activated protein under conditions standardized to process at least five liters of solution;

reacting the aldehyde-activated polysaccharide with the hydrazine-activated protein at a pH from 5 to 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained;

neutralizing unreacted aldehyde groups with adipic acid dihydrazide; and purifying the resulting solution under conditions standardized to process a volume of at least two liters,

whereby a meningococcal conjugate vaccine capable of stimulating an immune response is obtained in commercial volumes.

16. (Previously Presented) The method according to claim 15, wherein the aldehyde-activated polysaccharide is reacted with the hydrazine-activated protein at a ratio from 1:1.6 to 1:5.

17. (Currently Amended) The method according to claim 15, wherein said purifying the resulting solution comprises the step of diafiltrating the conjugate vaccine, whereby ~~substantially all~~ unreacted compounds and unconjugated polysaccharides are removed, yielding a purified conjugate vaccine.

18. (Previously Presented) The method according to claim 17, further comprising the step of concentrating the purified conjugate vaccine by tangential flow ultrafiltration, yielding a concentrated purified conjugate vaccine.

19. (Previously Presented) The method according to claim 18, further comprising the step of adding saccharose as a stabilizer to the concentrated purified conjugate vaccine, yielding a stabilized conjugate vaccine.

20. (Cancelled).